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IF GNITH CKMIND. APPI ICA HON NO. LILING DATE TIRSUNANI, LOSSENHAR PC10887AJAK 5329 Maria S. Brown 04/12/2001 09/834,098

06/17/2003 7590

Gregg C. Benson Pfizer Inc. Patent Department, MS 4159 Eastern Point Road Groton, CT 06340

EXAMINER MARX, IRENE

PAPER NUMBER ART UNIT

1651

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|  |   | Application No.  | Applicant(s)   |  |
|--|---|--|--|--|
|  |   | 09/834,098   | BROWN ET AL.   |  |
| •  | Office Action Summary   | Examiner   | Art Unit   |  |
|  |   | Irene Marx   | 1651   |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address  |   |  |  |  |
| Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM   |   |  |  |  |
| THE M - Extensions after S - If the j - If NO - Failure  | MAILING DATE OF THIS COMMUNICATION. sions of time may be available under the provisions of 37 CFR 1.1 SIX (6) MONTHS from the mailing date of this communication. period for reply specified above is less than thirty (30) days, a repl period for reply is specified above, the maximum statutory period to the reply within the set or extended period for reply will, by statute sply received by the Office later than three months after the mailing dipatent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, however, may a reply be tily within the statutory minimum of thirty (30) da will apply and will expire SIX (6) MONTHS from a course the application to become ABANDON! | mely filed ys will be considered timely. n the mailing date of this communication. ED (35 U.S.C. § 133). |  |
| Status   | : 1: ( ) Flad on 46   | Anril 2002   |  |  |
| 1)⊡  | Responsive to communication(s) filed on 16.7  |  |  |  |
| 2a) <u>⊡</u>   |   | nis action is non-final.   | prosecution as to the merits is  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. |   |  |  |  |
| -  | on of Claims  | Para   |  |  |
|  | 4) Claim(s) 1 and 3 is/are pending in the application.  |  |  |  |
|  | 4a) Of the above claim(s) is/are withdra  | wn from consideration.   |  |  |
| •  | Claim(s) is/are allowed.  |  |  |  |
|  | Claim(s) <u>1 and 3</u> is/are rejected.  |  |  |  |
|  | Claim(s) is/are objected to.  | l II a sa sa sa la sa  |  |  |
|  | Claim(s) are subject to restriction and/o   | or election requirement.   |  |  |
| Application Papers   |   |  |  |  |
| 9) The specification is objected to by the Examiner.  10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.   |   |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |  |  |  |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.   |   |  |  |  |
| If approved, corrected drawings are required in reply to this Office action.   |   |  |  |  |
| 12) The oath or declaration is objected to by the Examiner.  |   |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120  |   |  |  |  |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  |   |  |  |  |
| , —  | ☐ All b)☐ Some * c)☐ None of:   |  |  |  |
|  | 1. Certified copies of the priority documer   | nts have been received.  |  |  |
|  | 2. Certified copies of the priority documer   | nts have been received in Applica  | ation No   |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  |   |  |  |  |
| * ;  | * See the attached detailed Office action for a list of the certified copies not received.  |  |  |  |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).   |   |  |  |  |
| a) ☐ The translation of the foreign language provisional application has been received.  15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.                             |   |  |  |  |
| Attachme   |   |  |  |  |
| 1) Noti  | ice of References Cited (PTO-892)<br>ice of Draftsperson's Patent Drawing Review (PTO-948)<br>rmation Disclosure Statement(s) (PTO-1449) Paper No(s)  | 5) Notice of Inform  | nary (PTO-413) Paper No(s) nal Patent Application (PTO-152)  |  |
|  |   |  |  |  |

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<sup>4</sup> Art Unit: 1651

The amendment filed 4/16/03 is acknowledged. Claims 1 and 3 are being considered on the merits.

Claims 1 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague, indefinite and confusing in that it is directed to a "composition of matter" prepared in a detailed series of steps, wherein the mutants of a certain strain are indicated as "capable" of a certain process of biotransformation. However, the properties and purpose of the polypeptide which is recovered, and which appears to constitute the "composition of matter", are not defined with any particularity.

Claim 3 is vague, indefinite and confusing in the use of the phrase "is capable of allowing the separable elution of a fraction comprising a polypeptide". It is unclear what is intended, since this phrase does not constitute a positive limitation. The phrase is open to interpretation as to the circumstances of "capable of allowing" and of "separable elution. That the indicated size range is the size of the polypeptide recovered is not specified with any particularity.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.

Irene Marx

Primary Examiner

Art Unit 1651